3737

ATTORNEY DOCKET NO: 83815-1402

EXAMINER	Shawna Jeannine Shaw
GROUP	3737
APPLICANT	Laura M. McIntosh et al.
SERIAL NO:	10/089,314
FILED	August 5, 2002
FOR	NON-INVASIVE SCREENING OF SKIN DISEASES BY VISIBLE/NEAR-INFRARED SPECTROSCOPY

U.S. Patent and Trademark Office
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Crystal Plaza Two, Lobby, Room 1B03
Arlington, Virginia 22202
U.S.A.

Dear Sir:

Further to the Disclosure Submission Statement under 37 CFR 1.56 submitted on April 14, on review of this document, I am concerned that the covering letter did not indicate that we were first made aware of these references on April 8 when they were reported to us by our Australian associate responsible for the corresponding Australian patent application, AU 77662/00. These references were first cited by the Australian examiner in a letter dated April 5, 2005. Copies of these letters are enclosed herewith as supporting evidence. I hereby attest that these references were reported to the USPTO within 3 months of being cited as prior art during prosecution of a foreign patent application.

Regarding WO 98/46133, it is noted that the Australian examiner states in the office action that the claims pending in the Australian application which correspond substantially verbatim with those pending in USA are distinguished from this reference.

Regarding US Patent 5,836,872, it is noted that the abstract of this reference deals primarily with multispectral digital images of body surfaces which are compared to subsequent similar body images. A database is also described which contains a series of images from a lesion together with the medical history of that lesion. This database can then

be used for characterizing subsequent lesions. Finally, the abstract also mentions "classifying the features of [a] lesion according to the diagnostically useful classification of pigmented skin lesions". Specifically, this patent deals primarily with temporal-spatial distribution of light-absorbing characteristics of skin lesions, in particular, the depth of their subsurface extents. In other words, changes in the multispectral (red, green blue and infra-red) characteristics of lesions are monitored over time. These images can be used to reconstruct a 3-D surface map of the surface. This may then be used to estimate pigment depth and/or density, or to estimate features of other subsurface structures or processes (US Patent 5,836,872, column 16, lines 1-3). Thus, the majority of the document deals with methods of recording digital images of lesions such that the lesions are mapped to their particular body portion so that any changes to size, color or morphology of the lesion over time can be easily detected on comparison with the recorded images. Furthermore, multispectral images are taken so that changes to the distribution of pigment and other characteristics can also be monitored over time. This is not applicant's invention, which involves taking a spectrum of visible or near-IR light of a skin portion afflicted with a skin disease selected from the group consisting of: dysplastic melanocytic nevi; banal nevi; lentigines; actinic keratoses; seborrheic keratoses; basal cell carcinoma; and malignant melanoma; comparing that spectrum to a control skin portion and based on that comparison, determining what steps are needed next, for example, whether a biopsy is necessary or not. In the instant claims, an initial diagnosis of the skin lesion is done immediately, not based on changes over time. Furthermore, the differences between lesions that allow diagnosis with the present invention are based upon biochemistry, and are not morphological in nature. Thus it is not required to postulate a link between morphology and histology. In addition, the present invention is able to classify non-pigmented lesions, in addition to pigmented lesions.

As discussed above, US Patent 5,836,872 does mention a classification system which is discussed in column 25, lines 21 to 48 of US Patent 5,836,872. However, this

classification system is largely prophetic and basically states that a classification method could be created, for example, based on "a priori information about how morphologic and spectral features of pigmented cutaneous lesions correlate with microscopic pathological features thereof, a classification method may be employed by the invention that incorporates this a priori information into a classification scheme that would estimate the probability that a given cutaneous lesion belonged to a particular pathological class or diagnosis. Or for example, consider multispectral data and a priori information about the known spectral properties of certain pigments and other structures in the skin, then, a classification scheme could be employed by the invention that would classify each pixel as belonging to one, or possibly more than one, class..." Thus, while a classification scheme is envisioned, no formal classification scheme is taught. Furthermore, the envisioned scheme requires digital images for pixel analysis and/or morphological analysis of the lesion which is again not applicant's invention. Thus, US Patent 5,836,872 suggests that it might be possible to create a classification scheme but does not demonstrate that such a scheme would work. Furthermore, the schemes suggested by US Patent 5,836,872 require additional analysis, either digital or morphological, not found in the instant claims. Finally, US Patent 5,836,872 assumes a priori knowledge of the relationship between pigmentation and lesion histology, an assumption not required in the present invention.

Further and more favorable consideration is respectfully requested.

Respectfully submitted

Laura M. McIntosh et al.

PER: _____

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8 April 2005

BY FACSIMILE

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APR 18 2005
ADE & COMPANY

Dear Dr Williams,

re: NATIONAL RESEARCH COUNCIL OF CANADA
Australian Patent Application No. 77662/00
Title: NON-INVASIVE SCREENING OF SKIN DISEASES ...
Your ref: 083815-01407
Our ref: P400114

We refer to our letter of 31 March 2005.

Unfortunately the Examiner has now raised a second adverse report, a copy of which is enclosed.

Our comments on the objections raised in the report are as follows:

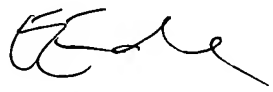
3. The Examiner has maintained the lack of unity objection on the basis that the common feature of the claims is not a novel feature. To support this the Examiner has raised two citations. In order to overcome the lack of unity objection, it will be necessary to show that each of the independent claims has a common novel feature and so we must show that the feature common to the claims is novel over the prior art. We request your instructions.

4. The Examiner has raised novelty and inventive step objections in relation to the prior art raised in item 3. We look forward to receiving your comments on the relevance of the prior art together with any further proposals for amendment as necessary.

We remind you that we are now in the period when monthly official late fees are payable at the time of responding to the Examiner's objections. The absolute deadline for placing this application in order for acceptance is 13 August 2005.

We look forward to receiving your instructions.

Yours sincerely
PATENT ATTORNEY SERVICES



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5 April 2005

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Your Ref : P400114

Examiner's report no. 2 on patent application no. 77662/00
by NATIONAL RESEARCH COUNCIL OF CANADA

Last proposed amendment no. 4

Dear Madam/Sir,

Thank you for the reply of 1 April 2005 to the last report. I have considered it and believe that there are lawful grounds of objection to the application. These grounds of objection are:

3. The specification does not comply with Section 40(4), as the claims do not relate to one invention only, a posteriori.

   The features of emitting a beam of visible or near-infrared light onto control and diseased portions of skin to provide reflected control, and disease, spectra that are compared is known from

   US 5836872 by Kenet et al
   WO 1998/046133 by Lui et al

   The characterising features of the independent claims are then not common and thus they lack unity of invention, a posteriori.

4. Kenet et al discloses exposing skin to white light, and up to infrared light, to obtain multispectral digital images that are compared to subsequently taken images, as well as comparison of global and local images of skin portions (equating to control and diseased portions of skin), to determine whether lesions from diseased skin are present. Databases of diseased skin are consulted, and built, from the information obtained from the compared multispectral images. Claims 1, 2, 8, 9, 12 and 13 are not novel and/or lack inventive step in the light of Kenet et al. It is considered common general knowledge to take a biopsy of a suspected diseased portion of skin.

   Lui et al discloses use of reflected white light, or near infrared light, spectra for determination of diseased skin by comparison of control and diseased skin portions. However, definitive determination of skin diseases is made by combining the reflected spectra comparison with fluorescent spectra also obtained, and thus the claims are considered to have novelty and inventive step over this citation.

You have until 13 August 2005 to overcome all of my objections otherwise your application will lapse.

You will need to pay a monthly fee for any response you file after 12 months from the date of the first report.

You will need to pay any annual continuation fees that apply. These will normally be first due five years from the filing date. Please note however that earlier commencement dates apply for divisional applications.

Information about fees may be obtained by phoning 1300 651010.

Yours faithfully,

STEPHEN CLARK
Examiner of Patents, Section A3
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